Panaji, 14th September, 1972 (Bhadra 23, 1894) SERIES I No. 24

# OFFICIAL GAZETTE

## GOVERNMENT OF GOA, DAMAN AND DIU

### GOVERNMENT OF GOA, DAMAN AND DIU

Industries and Power Department

**Notification**

1-233-69-IPD

In exercise of the powers conferred by section 30 of the Inland Steam Vessels Act, 1917, the Lieutenant Governor of Goa, Daman and Diu hereby makes the following amendment to the rules regulating the grant of certificates of service to Masters, Serangs, Drivers and Engineers of Inland Steam (power propelled) vessels promulgated under notification No. I & L/1545/65/3905 dated 26-8-1965, namely:

"the following item shall be inserted as item No. 6 to the Schedule I appended to the said notification:

"6. *Persons holding "Carta de Maquinista"*

(a) If a person is having a minimum service of eighteen months as a driver on vessels having engines of not less than 226 IHP, or 40 NHP, he may be issued with certificate of service as Second Class Driver (Steam).

(b) If a person is having a minimum service of twenty four months as a driver on vessels having engines of not less than 226 IHP or 40 NHP, he may be considered for issuing a certificate of service as First Class Driver (Steam)".

By order and in the name of the Lieutenant Governor of Goa, Daman and Diu.

*P. Noronha,* Under Secretary, Industries & Labour.

Panaji, 4th September, 1972.

Public Health Department

**Notification**

A-9/72-DHS/5576

Government of India. Ministry of Health, and Family Planning's Notification No. X-11014/12/72-D dated 5th June, 1972 published in the Gazette of India Part II, Section 3, Sub-section (ii), is hereby re-published for general public information.

*P. Noronha,* Under Secretary (Health).

Panaji, 29th August, 1972.

**Notification**

Whereas certain draft rules, as specified in column 2 of the Schedule annexed hereto, further to amend the Drugs and Cosmetics Rules, 1945, were published, as required by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in different issues of the Gazette of India (as specified in the corresponding entries in column 5 of the said Schedule) inviting all persons likely to be affected thereby to make objections or suggestions by the dates in the corresponding entries in column 7 of the Schedule aforesaid;

And Whereas the said Gazettes were made available to the public on the corresponding dates specified in column 6, of the Schedule aforesaid;

And Whereas the objections and suggestions received from the public on the said draft have been considered by the Central Government;

Now, Therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely: —

1. (1) These rules may be called the Drugs and Cosmetics Amendment Rules, 1972.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, in clause (ee) of rule 2.

(i) in sub-clause (ii), after the word 'medicine' the following shall be inserted, namely: —

", excluding the Homoeopathic system of medicine":

(ii) in sub-clause (iii) after the words 'medical register', the following shall be inserted, namely: —

", other than a register for the registration of Homoeopathic practitioner,";

(3) in rule 3A, after sub-rule (2) of the following sub-rule shall be inserted, namely: —

"(3) The functions of the laboratory in respect of condoms shall be carried out at the Central

Indian Pharmacopoeia Laboratory, Ghaziabad, and the functions of the Director in respect of the said condoms shall be exercised by the Director of the said Laboratory".

(4) after rule 32, the following rule shall be inserted namely: —

"2-A *Packing and Labelling of Homoeopathic medicine* No Homoeopathic medicine shall be imported unless it is packed and labelled in conformity with the rules in Part IX-A".

(5) in sub-rule (1) of rule 45, after the word 'drugs' the words and cosmetics shall be inserted;

(6) in rule 49, —

(i) in the first proviso for the words 'in the manufacture and' the words 'in the manufacture or' shall be substituted.

(ii) after the second proviso the following proviso shall be inserted, namely: —

"Provided further that any person appointed as Inspector in terms of the preceding proviso may be allowed to hold his post after the said period of four years, if the State Government is satisfied that he possesses adequate knowledge and competence as Inspector to inspect the manufacture of items mentioned in Shedule C".

(7) for rule 50, the following rule shall be substituted, namely: —

*"50 Controlling authority:* (1) All Inspectors appointed by the Central Government shall be under the control of an officer appointed in this behalf by the Central Government.

(2) All Inspectors appointed by the State Government shall be under the control of an officer appointed in this behalf by the State Government.

(3) For the purposes of these rules an officer appointed by the Central Government under sub-rule (1), or as the case may be an officer appointed by the State Government under sub-rule (2), shall be a controlling authority".

(8) for the proviso to sub-rule (3) of rule 59 the following proviso shall be substituted, namely: —

"Provided that if the applicant applies for the renewal of a licence after its expiry but within six months of such expiry the fee payable for renewal of such licence shall be rupees twenty plus an additional fee at the rate of rupees twenty per month or part, thereof, and in the case of itinerant vendor or an applicant desiring to open a shop in village or town having a population of 5000 or less the fee shall be rupees five plus an additional fee at the rate of rupees five per month or part thereof".

(9) for the proviso to rule 63 the following proviso shall be substituted, namely: —

"Provided that if the application for renewal of licence in force is made before its expiry or if the application is made within six months of its expiry after payment of additional fee, the licence shall continue to be in force until orders are passed on the application. The licence shall be deemed to have expired if application for its renewal is not made within six months after its expiry".

(10) in rule 65,

(i) for sub-rule (3) the following shall be substituted, namely: —

"(3) (1) The supply of any drug on a prescription of a registered medical practitioner shall be recorded at the time of supply in a prescription register specially maintained for the purpose and the serial number of the entry in the register shall be entered on the prescription. The following particulars shall be entered in the register: —

(a) serial number of the entry,

(b) the date of supply,

(c) the name and address of the prescriber,

(d) the name and address of the patient,

(e) the name of the drug or preparation and the quantity or in the case of a medicine made up by the licensee, the ingredients and quantities thereof,

(f) in the case of a drug specified in Schedule C, Schedule H or Schedule L the name of the manufacturer of the drug, its batch number and the date of expiry of potency, if any,

(g) the signature of the qualified person by or under whose supervision the medicine was made up or supplied.

Provided that in the case of drugs which are not compounded in the premises and which are supplied from or in the original containers, the particulars specified in items (a) to (g) above may be entered in a cash or credit memo book, serially numbered and specially maintained for this purpose:

Provided further that if the medicine is supplied on a prescription on which the medicine has been supplied on a previous occasion and entries made in the prescription register, it shall be sufficient if the new entry in the register includes a serial number, the date of supply, the quantity supplied and a sufficient reference to an entry in the register recording the dispensing of the medicine on the previous occasion.

Provided further that it shall not be necessary to record the above details in the register or in the cash or credit memo particulars in respect of: —

(i) any drugs supplied against prescription under the Employees State Insurance Scheme if all the above particulars are given in that prescription, and

(ii) any drug other than that specified in Schedule C, E or L if it is supplied in the original unopened container of the manufacturer and if the prescription is duly stamped at the time of supply with the name of the supplier and the date on which the supply was made and on condition that the provisions of sub-rule (4) (3) of this rule are complied with.

(2) The option to maintain a prescription register or a cash or credit memo book in respect of drugs and medicines which are supplied from or in the original container, shall be made in writing to the Licensing Authority at the time of application for the grant or renewal of the licence to sell by retail.

Provided that the Licansing authority may require records to be maintained only in prescription register if it is satisfied that the entries in the carbon copy of the cash or credit memo book are not legible".

(i) after sub-rule (11), the following sub-rule shall be inserted, namely: —

"(11-A) No person dispensing a prescription containing substances specified in Schedule H or L, may supply any other preparation, whether containing the same substance or not, in lieu thereof".

(ii) in sub-rule (12), for the words — "Substances specified in Schedule E", the following words shall be substituted, namely: —

"Substances specified in Schedule E other than in a form ready for internal or external use and".

(11) after rule 65, the following rule 65-A shall be inserted, namely: —

*"65-A Additional information to be furnished by an applicant for licence or a licence to the Licensing Authority:* — The applicant for the grant of a licence or any person granted a licence under this Part shall, on demand, furnish to the licensing authority, before the grant of the licence or during the period the licence is in force, as the case may be, documentary evidence in respect of the ownership of occupation or rental or other basis of the premises, specified in the application for licence or in the licence granted, constitution of the firm, or any other relevant matter which may be required for the purpose of verifying the correctness of the statements made by the applicant or the licensee, while applying for or after obtaining the licence, as the case may be".

(12) in rule 66 in sub-rule (1), for the proviso, the following proviso shall be substituted, namely: —

"Provided that, where such failure or contravention is the consequence of an act or omission on the part of an agent or employee, the licence shall not be cancelled or suspended if the licensee proves to the satisfaction of the licensing authority: —

(a) that the act or omission was not instigated or connived at by him or, if the licensee is a firm or company, by a partner of the firm or a director of the company, or

(b) that he or his agent or employee had not been guilty of any similar act or omission within twelve months before the date on which the act or omission in question took place, or where his agent or employee had been guilty of any such act or omission, the licensee had not or could not reasonably have had, knowledge of that previous act or omission, or

(c) if the act or omission was a continuing act or omission, he had not or could not reasonably have had knowledge of that previous act or omission, or

(d) that he had used due diligence to ensure that the conditions of the licence or the provisions of the Act or the rules thereunder were observed".

(13) for the proviso to sub-rule (2) of rule 67-A the following proviso shall be substituted, namely: —

"Provided that if the applicant applies for renewal of licence after its expiry but within six months of such expiry the fee payable for renewal of such licence shall be rupees five plus an additional fee at the rate of rupees five per month or part thereof.";

(14) for the proviso to rule 67-E the following proviso shall be substituted, namely: —

"Provided that if the application for renewal of a licence in force is made before its expiry or if the application is made within six months of its expiry, after payment of additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed to have expired if application for its renewal is not made within six months after its expiry".

(15) After rule 67-G the following rule shall be inserted, namely: —

*"67-G Additional information to be furnished by an applicant for licence or a licencee to the Licensing authority:* — The applicant for the grant of a licence or any person granted a licence under this Part shall, on demand, furnish to the licensing authority, before the grant of the licence or during the period the licence is in force, as the case may be, documentary evidence in respect of the ownership or occupation on rental or other basis of the premises, specified in the application for licence or in the licence granted, constitution of the firm, or any other relevant matter, which may be required for the purpose or verifying the correctness of the statements made by the applicant or the licensee, while applying for or after obtaining the licence, as the case may be".

(16) in rule 67-H, in sub-rule (1), for the proviso, the following proviso shall be substituted, namely:—

"Provided that, where such failure or contravention is the consequence of an act or omission on the part of an agent or employees, the licence shall not be cancelled or suspended if the licensee proves to the satisfaction of the licensing authority: —

(a) that the act or omission was not instigated or connived at by him or, if the licensee is a firm or company, by a partner of the firm or a director of the company, or

(b) that he or his agent or employee had not been guilty of any similar act or omission within twelve months before the date on which the act or omission in question took place, or where his agent or employee had been guilty of any such act or omission, the licensee had not or could not reasonably have had, knowledge of that previous act or omission, or

(c) if the act or omission was a continuing act or omission that he had not or could not reasonably have had knowledge of that previous act or omission, or

(d) that he had used due diligence to ensure that the conditions of the licence or the provisions of the Act or the rules thereunder were observed".

(17) in rule 69, —

for sub-rule (2), the following sub-rule shall be substituted, namely: —

"(2) Every application in Form 24-B shall be accompanied by a fee of rupees forty and an inspection fee of rupees ten for first inspection or rupees five in the case of inspection for renewal of licences and every application in Form 24 shall be accompanied by a fee of rupees two hundred and an inspection fee of rupees two hundred and an inspection fee of rupees fifty for first inspection or rupees twenty-five in the case of inspection for renewal of licences.

(ii) for sub-rule (3) the following sub-rule shall be substituted, namely: —

"(3) If a person applies for the renewal of a licence after its expiry but within six months of such expiry, the fee payable for the renewal of such licence shall be in the case of Form 24.B, rupees twenty per month or part thereof in addition to the inspection fee and, in the case of Form 24, rupees two hundred plus an additional fee at the rate of rupees one hundred per month or part thereof in addition to the inspection fee".

(18) in sub-rule (1) of rule 69-A before the Explanation, the following proviso shall be inserted, namely: —

"Provided that if the applicant for the renewal of a licence after its expiry but within six months of such expiry the fee at the rate of rupees fifty per month or part thereof".

(19) in rule 71-A for clause (2) the following clause shall be substituted namely: —

"(2) the factory premises shall comply with the conditions prescribed in Schedule M, and".

(20) for the proviso to rule 72 the following proviso shall be substituted, nemely: —

"Provided that if the application for the renewal of a licence is made before its expiry, or if the application is made within six months of its expiry, after payment of additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed to have expired if the application for its renewal is not made within six months of its expiry".

(21) for the proviso to rule 73-AA the following proviso shall be substituted, namely: —

"Provided that if the application for the renewal of a licence is made before its expiry, or if the application is made within six months of its expiry, after payment of the additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed to have expired if the application for its renewal is not made within six months of its expiry".

(22) for the proviso to rule 75 the following proviso shall be substituted, namely: —

"Provided that if the applicant applies for renewal of licence after its expiry but within six months of such expiry, the fee payable for renewal of the licence shall be rupees three hundred plus an additional fee at the rate of rupees two hunred per month in addition to the inspection fee".

(23) in sub-rule (*1*) of rule 75-A before the Explanation, the following proviso shall be inserted namely: —

"Provided that if the applicant applies for the renewal of a licence after its expiry but within six months of such expiry the fee payable for renewal of the licence shall be rupees three hundred plus an additional fee at the rate of rupees two hundred per month or a part thereof."

(24) for the proviso to rule 77 the following proviso shall be substituted, namely: —

"Provided that if the application for the renewal of a licence is made before its expiry, or if the application is made within six months of its expiry, after payment of additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed to have expired if the application for its renewal is not made within six months of its expiry."

(25) for the proviso to rule 83-AA the following proviso shall be substituted, namely: —

"Provided that if the application for the renewal of a licence is made before its expiry, or if the application is made within six months of its expiry, after payment of the additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed to have expired if the application for its renewal is not made within six months of its expiry."

(26) after rule 84, the following rule shall be inserted, namely: —

"*84-A. Provision for appeal to the State Government by party whose licence has not been granted or renewed.* Any person who is aggrieved by the order passed by the licensing authority refusing to grant or renew a licence in Form 25, 25-A, 25-B, 26, 26-A, 26-B, 28 and 28-A may within thirty days from the date of receipt of such order, appeal to the State Government and the State Government may, after such enquiry into the matter as it considers necessary and after giving the said person an opportunity for representing his views in the matter, make such order in relation thereto as it thinks fit.

"*84-AA. Additional information to be furnished by an applicant for licence or a licensee to the licensing authority.*

The application for the grant of a licence or any person granted a licence under this Part shall, on demand, furnish to the licensing authority, before the grant of the licence or during the period the licence is in force, as the case may be, documentary evidence in respect of the ownership or occupation on rental or other basis of the premises, specified in the application for licence or in the licence granted, constitution of the firm, or any other relevant matter, which may be required for the purpose of verifying the correctness of the statements made by the applicant or the

licensee, while applying for or after obtaining the licence, as the case may be."

(27) for sub-rule (3) of rule 85-B the following sub-rule shall be substituted, namely: —

"(3) If a person applies for renewal of a licence after its expiry but within six months of such expiry, the fee payable for the renewal of such a licence shall be —

(i) rupees forty plus an additional fee at the the rate of rupees ten per month or part thereof for the manufacture of —Homoeopathic mother tinctures and potentised preparations; and

(ii) rupees twenty plus an additional fee at the rate of rupees ten per month or part thereof for the manufacture of potentised preparations only."

(28) for the proviso to rule 55-F, the following proviso shall be substituted, namely: —

"Provided that if the application for renewal of a licence in force is made before its expiry or if the application is made within six months of its expiry, after payment of additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed to have expired if application for its renewal is not made within six months of its expiry."

(29) after rule 85-H, the following rule shall be inserted, namely: —

*"85-HH Additional information to be furnished by an applicant for the licence or a licensee to the licensing authority.* The applicant for the grant of licence or any other person granted a licence under this Part shall, on demand, furnish to the licensing authority, before the grant of the licence is in force, as the case may be, documentary evidence in respect of the ownership or occupation in rental or other basis of the premises, specified in the application for licence or in the licence granted, constitution of the firm, or any other relevant matter which may be required for the purpose of verifying the correctness of the statements made by the applicant or the licensee, while applying for or after obtaining the licence as the case may be."

(30) in rule 96, after sub-rule (1) the following sub-rule shall be inserted, namely: —

"(1-A) (a) The particulars to be printed or written on the label of condoms shall be as specified in Schedule R.

(b) The following further particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the inner-most container and on every other covering in which the container containing the contraceptives, other than condoms, is packed, namely: —

(i) the date of manufacture

(ii) the date upto which the contraceptive is expected to retain its properties

(iii) the storage conditions necessary for preserving the properties of the contraceptive up to the date indicated in clause (ii).

Provided that for oral contraceptives it shall be sufficient to display on the label of the container the date of manufacture only."

(31) in rule 106-A, in sub-rule (B), under clause (ii), the following Explanation shall be inserted at the end, namely: —

*Explanation:* — This clause shall not apply to a Homoeopathic mother tincture manufactured outside India".

(32) for sub-rule (2) of rule 138, the following sub-rule shall be substituted, namely: —

"(2) If a person applies for the renewal of a licence after expiry but within six months of such expiry, the fee payable for the renewal of such licence shall be rupees two hundred plus an additional fee at the rate of rupees one hundred per month or a part thereof.

Provided that in the case of small scale manufacturer employing not more than five persons the fee payable for the renewal of such licence after its expiry but within six months of such expiry shall be rupees forty plus an additional fee at the rate of rupees twenty per month or a part thereof".

(33) for the proviso to rule 140 the following proviso shall be substituted, namely: —

"Provided that if the application for renewal of a licence in force is made before its expiry or if the application is made within six months of its expiry, after payment of additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed to have expired, if application for its renewal is not made within six months of its expiry".

(34) after rule 142, the following rule shall be inserted, namely: —

*"142-A Additional information to be furnished by an applicant for licence or a licensee to the licensing authority.* The applicant for the grant of a licence or any person granted a licence under this Part shall, on demand, furnish to the licensing authority, before the grant of the licence or during the period the licence is in force, as the case may be, documentary evidence in respect of the ownership or occupation on rental or other basis of the premises, specified in the application for licence or in the licence granted, constitution of the firm, or any other relevant matter, which may be required for the purpose of verifying the correctness of the statements made by the applicant or the licensee, while applying for or after obtaining the licence as the case may be".

(35) after rule 145, the following rules shall be inserted, namely: —

*"145-A Form of intimation for purpose of taking samples of cosmetics.* Where an Inspector takes a sample of a cosmetics for the purpose of test or analysis, he shall intimate such purpose in writing in Form 17 to the person from whom he takes it.

*145-B Form of receipt for seized cosmetics.* A receipt by an Inspector for the stock of any cosmetic seized under clause (c) of sub-sec-

tion (1) of section 22 of the Act, shall be in Form 16";

(36) in Schedule A:

(i) or Forms 16 or 17, the following Forms shall be substituted, namely: —

FORM 16

(See rules 55 and 145B)

**Receipt of stock of drugs/cosmetics seized under Section 22(1) of the Act**

The stock of drugs/cosmetics detailed below has this day been seized by me under the provisions of clause (c) of sub-section (1) of section 22 of the Drugs and Cosmetics Act 1940, from the premises of ... situated at ...

Date ... Inspector ...

Details of drugs/cosmetics seized

Date ... Inspector ...

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FORM 17

(See rules 56 and 145-A)

**Intimation to person from whom sample is taken**

To

.....
.....
.....

I have this day taken from the premises of ... situated at ... samples of the drugs/cosmetics specified below for the purpose of test or analysis.

Date ... Inspector ...

Details of samples taken

Date ... Inspector ...

(ii) in Form 21,

(a) for para 1, the following shall be substituted namely: —

"I ... is hereby licensed to sell, stock or exhibit for sale or distribute by retail the following categories of drugs specified in Schedules C and C(1) to the Drugs and Cosmetics Rules 1945* and to operate a pharmacy on the premises situated at ... subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules therunder".

(b) for para 4, the following shall be substituted, namely: —

"4. Categories of drugs ...".

(c) after the entry "Licensing Authority", the entry *Delete if not applicable" shall be inserted."

(37) in Schedule F,

(i) in part I, for Section (B), the following shall be substituted, namely: —

«B Provisions Applicable to vaccinum Variolae (Smallpox Vaccine)

DEFINITIONS

1. **International name and proper name.** — The International name of the preparation shall be 'Vaccinum Variolae' and the proper name shall be "Smallpox Vaccine".

2. **Descriptive definition.** — Vaccinum Variolae (Smallpox Vaccine) is a dried preparation of vaccinia virus grown in the skin of living animals or in the membranes of the chick embryo or in the vimro cultures of suitable tissues. The preparation shall satisfy all the requirements formulated below.

3. **International standard and reference preparation.** — The International Reference Preparation of Smallpox Vaccine (Established in 1962) is dispensed in ampoules containing 14 mg of freeze-dried smallpox vaccine. This reference preparation is in the custody of the International Laboratory for Biological Standards, States Serum Institute, Copenhagen. The International Reference Preparation is intended for the calibration of reference preparation for use in this country in the manufacture and laboratory control of Smallpox Vaccine.

4. **Terminology.**

(1) *Primary seed lot* means a quantity of virus adapted to, and grown on the skin of a living animal, which has been processed together and has a uniform composition.

(2) *Secondary seed lot* means a quantity of virus grown in the skin of living animals or in the chorioallantoic membranes of chick embryos or in tissue cultures, which is uniform with respect to composition and is not more than 5 passages removed from a primary seed lot.

(3) *Single harvest* means a quantity of material harvested from one animal or a quantity of material harvested from a group of chick embryos or tissue cultures inoculated, incubated and harvested together.

(4) *Bulk material* means the materials at any stage after harvesting and before filling into final containers. Bulk material may be prepared from one or a number of single harvests.

(5) *Final bulk* means a quantity of vaccine after completion of preparations for filling and present on the container from which the final containers are filled.

(6) *Filling lot (final lot)* means a collection of sealed final containers that are homogeneous with respect to the risk of contamination during filling or drying. A filling lot shall, therefore, have been filled in one working session and have been dried together.

(7) *Pock-forming unit* means the smallest quantity of virus suspension that will produce a single pock on the chick chorioallantoic membrane.

(8) *Plague-Forming unit (PFU)* means the smallest quantity of virus suspension that will produce a single primary plague in monolayer cell cultures.

5. **General manufacturing requirements.**

Subject to the other provisions of the rules the manufacturer of Smallpox Vaccine shall maintain the staff, premises and equipment as laid down in Schedule M and shall also comply with the provisions contained in Part I A) of this Schedule in so far as it is applicable to the manufacture of Smallpox Vaccine.

6. **Production Control.**

(A) *Control of Source materials Virus strains.*

(1) The strains of virus used in the production of all seed lots shall be identified by historical records. They shall have been shown to the satisfaction of the licensing authority to yield immunogenic vaccines which produce typical vaccinal lesions in the skin of man followed by insusceptibility to subsequent challenge by revaccination with a strain of virus known to protect man against variola. The strain shall produce a characteristic vestcular eruption in the skin of rabbits and reproducible characteristic pock lesions in the chorioallantoic membrane of chick embryos. In addition, the vaccine strains shall be characterized by serological tests and animal inoculation.

(2) Records shall be maintained of all tests made periodically for verification of strain character.

(3) The strain used for vaccine production should be one that has never shown a greater tendency to produce generalised lesions or lesions of the nervous system in either man or animals than other strains of vaccinia virus which have been found to be satisfactory without producing severe local lesions and marked systemic disturbance. Strains of so-called 'neurovaccine' shall be excluded.

7. **Animals or tissues for the production of seed virus and vaccine.**

(1) Only healthy animals or tissues from healthy animals, susceptible to ectodeermal inoculations with vaccinia virus, or chick embryos obtained from healthy flocks shall be used for vaccine production. They shall conform to all the requirements given Para 10 of these standards. If cell cultures are used for vaccine production they shall be shown to be free from detectable adventitious agents.

(2) Different species of animals may be used for vaccine production or for preparing seed virus. Calves, sheep, buffaloes, donkeys and rabbits may be used successfully.

(3) The chorioallantoic membrane of the developing chick embryo and tissues from the embryos or young animals of susceptible species may also be suitable for virus propagation.

8. **Seed lot system.**

(1) A Primary seed lot shall be used as original material for the preparation of a Secondary seed lot. The Secondary seed lot shall be not more than five passages removed from a Primary seed lot. If vaccine is produced in the skin of a living animal the Secondary seed lot shall be prepared from the Primary seed lot without passage in chick embryos or tissue cultures. Vaccine shall be prepared from a seed lot without intervening passage.

(2) Seed lots should be maintained either in dried, frozen, or glycerinated forms. If a glycerinated seed lot is used it shall be kept continuously at a temperature below O°C.

9. **Tests on seed lots for the presence of extraneous micro-organisms.**

(1) The seed lot in the dillution used as inoculum for the production of vaccine in the skin of animals, shall satisfy the requirements of para 14 of these standards.

(2) The seed lot used for the production of vaccine in chick embryos or in tissue cultures shall after rehydration if applicable, satisfy the requirements of para 14 of these standards.

10. (B) *Production precautions.*

The precautions to be taken in the production of Smallpox Vaccine in matters relating to cleanliness of the premises, rooms, apparatus, equipments and materials, and the precautions against contamination shall be such as to ensure the purity, sterility and strength of the Vaccine and shall be approved by the licensing authority, with the following additional precautions, namely: —

(1) *Where Vaccines produced in the skin of living animals.*

(a) The animals shall be freed of ectoparasites, and each animal shall be kept in quarantine under veterinary supervision for at least two weeks prior to the inoculation of the seed virus. Before inoculation the animals shall be cleaned and thereafter kept in scrupulously clean stalls until the vaccinal material is harvested.

(b) During a period of five days before inoculation and during incubation the animals shall remain under veterinary supervision. They shall remain free from any sign of disease, and daily rectal temperatures shall be recorded. If any, abnormal rise in temperature occurs, of if any clinical sign of disease is observed the production of vaccine from the group of animals concerned shall be suspended until the cause of these irregularities has been resolved. The prophylactic and diagnostic procedure adopted to exclude the presence of infectious disease shall be submitted for approval, to the licensing authority.

(c) The inoculation of seed virus shall be made on such parts of the animal as are not liable to be soiled by urine and faeces. The surface used for inoculation shall be so shaved and cleaned as to procure the nearest possible approach to surgical asepsis. If any antiseptic substance deleterious to the virus is used in the cleaning process it shall be removed by thorough rinsing with sterile water prior to inoculation. During inoculation the exposed surface of the animal not used for inoculation shall be covered with sterile covering.

(d) Before the collection of the vaccinal material, any antibiotic shall be removed and the inoculated area shall be subjected to a repetition of the cleaning process. The uninoculated shall be covered with sterile covering.

(e) Before harvesting, the animal shall be killed painlessly. The animals shall be exsanguinated before harvesting to avoid heavy admixture of the vaccinal material with blood.

(f) The vaccinal material from each animal shall be collected separately with aseptic precautions.

(g) All animals used in the production of vaccine after being killed shall be examined by autopay. If evidence of any generalized or systemic disease other than vaccinia is found, the vaccinal material from that animal shall be discarded. If the disease is considered to be a communicable one, the harvest from the entire group of animals exposed shall be discarded.

(2) *Where Vaccines produced in the chick embryo:* —

(a) Only eggs from flocks known to be free from disease, including avian leucosi, shall be used.

(b) In particular, it is desirable that the eggs should be derived from flocks free from salmonella pullorum, Mycobacterium tuberculosis, Rous virus, mycoplama and other agents pathogenic for chickens.

(c) Living embryos after incubation for a suitable period shall be inoculated with seed virus which shall satisfy the requirements of paras 8 and 9 of these standards. After further incubation for a suitable period, the vaccinal material shall be harvested with aseptic precautions.

(3) *Where Vaccines produced in tissue culture:* —

(a) Only primary tissue cultures from animals known to be free from disease shall be used. The virus shall be drawn and harvested with aseptic precautions. No material of human origin shall be added to the cultures at any stage.

(b) Suitable antibiotics in minimum concentrations required for sterility may be used but the use of penicillin and streptomycin is prohibited.

**11. Control of the bulk material.**

*Initial treatment.*

(1) The vaccinal material harvested from the skin of each animal shall be subjected to a treatment designed to reduce its contents of living extraneous micro-organisms. If this is necessary, it should satisfy the requirements of para 14. No antibiotics shall be added to the bulk material.

(2) The treatment of the vaccine may consist of the addition of a suitable antibacterial substance or of the removal of micro-organisms by centrifugation.

(3) Vaccinal material collected from chick embryos or tissue cultures does not need such treatment, but glycerol or an antibacterial substance should be added as a precaution against later contamination.

**12. Final bulk.**

(1) After the initial treatment the vaccine may be subjected to additional processes before dilution of the bulk material.

(2) Before making up a final bulk, it should be necessary to do preliminary tests on the single harvests for potency and for the presence of living extraneous micro-organisms.

**13. Tests for virus concentration on the final bulk.**

The final bulk pass the test for virus concentration described in para 24 of these standards.

**14. Tests for the presence of living extraneous micro-organisms in the Final bulk prepared in the skin of living animals.**

The final bulk shall pass the following tests for the presence of living extraneous micro-organisms, unless these tests have already been passed by each of the single harvests represented in the final bulk.

**15. Tests for total hectarial content.**

(1) Suitable dilutions of L:10 and L:100 of the final bulk shall be made in a suitable diluent not deleterious to living bacteria. At least 1 ml samples of each dilution shall be cultured on nutrient-broth-agar plates. The plates shall be incubated for 72 hours between 15°C and 22°C and for a further period of 48 hours between 35°C and 37°C. From the number of colonies appearing on the plates the number of living bacteria in 1 ml of the final bulk shall be calculated. If this number exceeds 500, the final bulk shall be subjected to further treatment or be discarded.

(2) Suitable control plates containing higher dilutions of the final bulk shall be included in this test in order to make sure that the number of colonies appearing on the test plates has not been influenced by the inhibitory action of any preservative present in the final bulk.

**16. Test for the presence of Escherichis Coli.**

At least three 1 ml samples of a 1:10 dilution of the final bulk shall be cultured in three Mc Conkey liquid media tubes containing 10 ml of the medium for differentiating *E. coli* from other bacteria. The tubes shall be incubated for 48 hours at 35°C to 37°C. If *E. coli* is detected, the final bulk shall be subjected to further treatment or be discarded.

**17. Test for the presence of haemolytic streptococci, coagulase-positive staphyloccoci, or any other pathogenic micro-organisms which are known to be harmful if introduced into the human body by the process of vaccination.**

(1) Undiluted final bulk or vaccine of 0.1 ml each shall be cultured on three blood agar plates and the plates should be incubated at 35° to 37°C for 2 days. The Colones appearing after incubation shall be examined critically for *B. anthracis, haemolytic streptococci,* Coagulase positive *Staphylococci* or any other pathogenic micro organisms. If any of these organisms are detected they shall be subjected to confirmatory test.

(2) If any of the organisms mentioned are detected, the final bulk shall be subjected to further treatment or be discarded.

**18. Test for the presence of Clostridium tetani and other pathogenic spore-forming anaerobes.**

(1) 0.5 ml. of undiluted final bulk or vaccine shall be added in flasks containing 50 ml. of Robertson's Cooked meat medium, the flusks shall then be held at 65°C for one hour and then incubated at 35° to 37° for at least one week. At least two flasks shall be used for each test.

(2) In case of any suspected growth, subcultures shall be made on two plates of a suitable medium which shall be incubated anaerobically at the same temperature. All anaerobic colonies shall be examined and identified and if *Cl. tetani* or other pathogenic spore-forming anaerobes are present the final bulk shall be discarded.

(3) Organisms resembling pathogenic clostridia found in the tube culture from which the subculture was made may be tested for pathogenicity by inoculation into animals as follows: Groups of not less than two guinaepigs and five mice are used for each

tube culture to be tested. O. 5 ml. of the culture is mixed with 0.1 ml of a freshly prepared 4 percent solution of calcium chloride and injected intramuscularly into each of the guinea-pigs; 0.2 ml of the culture mixed with 0.1 ml of this calcium chloride solution is injected intramuscularly into each of the mice. The animals are observed for one week. If any animals develops symptoms of tetanus, or if any animal dies as a result of infection with spore-forming anaerobes, the final bulk should be discarded.

(4) If other methods are used for this test, they should have been demonstrated to the satisfaction of the licensing authority to be at least equally effective for detecting the presence of *Cl. tetani* and other pathogenic spore-forming anaerobes.

**19. Test for bacteriological sterility of the final bulk prepared in chick embryos or in tissue cultures.**

Each final bulk shall be tested for bacterial sterility according to the requirements given in the Indian Pharmacopoeia for the time being. If growth appears in any of the cultures the final bulk shall be discarded or the test repeated. The final bulk shall be discarded if the same type of organism appears in more than one test, but no final bulk shall be passed unless the final test shows no growth throughout.

### Filling and containers

**20. Filling rooms.**

Filling shall be performed in rooms reserved for this purpose. These shall be sterile rooms equipped specifically for transferring measured quantities of finished biological substances from bulk containers to the final containers. Strict dust control measures and aseptic techniques shall be enforced to ensure that the product is not contaminated during the filling process.

**21. Filling procedures.**

(1) Filling operations shall be conducted in such a way as to avoid any contamination or alteration of the product. They shall take place in areas that are completely separate from those in which living micro-organisms, including viruses, are handled.

(2) The filling process shall be checked at least twice each year at the end of a working day by filling not less than 500 ampoules with a nutrient medium containing no antibiotics or bacteriostatic substances and incubating the complete batch of filled ampoules. Not more than 1 percent of the ampoules filled in this way should show signs of contamination and all contaminants should be identified.

(3) All containers of the final vaccine shall be shown to be sterile before filling and shall be made of a material demonstrated, to the satisfaction of the licensing authority, to have no deleterious effect on the vaccine.

(4) Containers of dried vaccine shall be hermetically sealed under vaccum or after filling with pure, dry, oxygen- free nitrogen or any other gas not deleterious to the vaccine.

(5) All hermetically sealed containers shall be tested for leaks after sealing. All defective containers shall be discarded.

(6) Single and multiple-dose containers may be used. Each container of dry vaccine should be issued together with an ampoule of sterile reconstituting fluid. This fluid may contain glycerol and/or some suitable antiseptic substance. The containers shall be issued in a form that renders the process of reconstitution as simple as possible.

### Control Tests of Final Product

**22. Identity test.**

(1) An identity test shall be performed on at least one labelled container from each filling lot by appropriate methods.

(2) The test for virus concentration as described in para 24 may serve as an identity test.

(3) A test may also be made in the scarified skin of rabbits. Suitable dilutions of vaccine shall be applied on scarified areas of skin. After four to seven days the vaccine should produce lesions characteristic of vaccinia.

**23. Tests for virus concentration on vaccine in final containers.**

(1) A test for virus concentration shall be made on each filling lot in accordance with the requirements described in para 24. For this purpose the dried vaccine shall be reconstituted to the form in which it is to be used for human inoculation before the test is made.

(2) Tests shall be done in parallel with a reference vaccine which has been calibrated against the International Reference Preparation of Smallpox Vaccine.

**24. Test for virus concentration in membranas of chick embryos.**

At least ten chick embryos, each of about 12 day's incubation, shall be divided into two equal groups. To the chorio-allantoic membrane of each embryo of the first group 0.1 ml or 0.2 ml of a suitable dilution of the vaccine shall be applied. To the membrane of each of the second group of embryos 0.1 ml or 0.2 ml of another suitable dilution of the vaccine shall be applied. After the optimal time of incubation of the total number of discrete specific lesions shall be counted on the membrane of each embryo. The dilutions shall be so chosen that the membranes of at least one of the groups yield countable numbers of lesions exceeding ten per membrane. From the number of lesions counted in this group and from dilution and volumes used, the number of pock-forming units in one ml of the undiluted vaccine shall be calculated. This number shall exceed $1 \times 10$.

**25. Other tests.**

Tests for virus concentration in the scarified skin of rabbits shall also be used provided it has been shown that the results correlate with those obtained using the membranes of chick embroyos.

**26. Tests for the presence of extraneous living micro-organisms in the vaccine in final containers.**

Not less than four final containers (or not less than 10 if single-dose containers) giving a total pooled quantity which is equivalent to a volume of not less than 0.5 ml shall be taken at random from

each filling lot in such a manner that all stages of the filling from the bulk container shall be represented. For this purpose the dried vaccine shall be reconstituted to the form in which it is to be used in human inoculation. The vaccine thus collected shall pass the test described in paras 15 and 19, whichever is applicable.

27. **Innocuity test.**

Each filling lot shall be tested for abnormal toxicity by appropriate tests involving injection into rabbits. The tests shall be approved by the licensing authority. Mice and guinea-pigs may also be used for this test.

28. **Heat-resistance test on dried vaccine.**

At least one container of fried vaccine from each filling lot shall be incubated at a temperature of not less than 37° C for not less than 4 weeks and tested for virus concentration. The vaccine passes the test if the requirements described in para 24 are fulfilled and at least one tenth of the virus concentration is retained.

29. **Preservatives and other substances added.**

No antibiotics shall be added to Smallpox Vaccine. If the reconstituted dried vaccine contains preservatives or other added substances such substances shall have been shown, to the satisfaction of the licensing authority, to have no deleterious effect on the product in the amounts present and to cause no untoward reactions in vaccinated subjects. If phenol is present, its concentration shall not exceed 0.5 percent. Further, the substance used shall fulfil the requirements of the Indian Pharmacopoeia.

Miscellaneous

30. **Records.**

Records shall be permanent and clearly indicate all steps in processing, testing, filling and distribution. Written records shall be kept of all tests irrespective of their results. The records shall be maintained in a manner approved by the licensing authority. The records shall be retained throughout the period of a lot or a batch of the vaccine has been given a date of expiry and be available at all times for inspection by the Inspector.

31. **Sampling.**

Records shall be maintained of the complete passage history of all cultures kept by the manufacturer. The cultures shall be labelled and stored in a safe, orderly manner.

32. (1) **Labelling.**

(a) Subject to the other provisions of these rules, the label on the container shall show the following, namely: —

(i) the name of the vaccine (i.e. the International name or the proper name).

(ii) the principal place of business of the manufacture,

(iii) the Batch number or the lot number, and

(iv) the total number of doses in the container.

(b) the label on the package shall, in addition to the information shown on the label of the container, give the following particulars: —

(i) the name and address of the manufacturer,

(ii) the manufacturing licence number being preceded by the words "Manufacturing licence Number" or "Manufacturing Licence No." or "M.L." when the vaccine has been manufactured in this country.

(iii) the date of manufacture and the date of expiry.

(iv) the precautions necessary for preserving the properties of the vaccine, and

(v) if any antiseptic or preservative has been added, the nature and percentage thereof.

(2) The following additional information shall be given in the leaflet accompanying the package, namely: —

(a) conditions of storage,

(b) instructions for use,

(c) the method of reconstitution of the vaccine, and

(d) a statement that, after rehydration of the dried vaccine, the vaccine should be used within six hours.

33. **Storage conditions.**

Before being distributed by the manufacturing establishment; or before being issued from a depot for the maintenance of reserves of vaccine, all dried vaccines in their final containers shall be kept constantly at a temperature below + 10°C.

34. **Expiry date.**

The date after which dried vaccine may not be used shall be not more than 36 months after passing the last test for virus concentration. The expiry date shall not be more than 36 months after passing the last test for virus concentration. The expiry date shall not, however, be more than twelve months for dried vaccine from the date on which the vaccine was issued by the manufacturer".

(ii) In part IX, under the heading 'Liver Injection Crude': —

(a) in para 4(b) after the words 'Evaporate to dryness in a water bath' the word "dry" shall be inserted;

(b) for para 4(e) the following para shall be substituted, namely: —

"(e) Sterility test — Liver Injection Crude shall comply with the sterility test laid down for 'Injections' in the edition of the Indian Pharmacopoeia for the time being".

(c) for para 4(f) the following para shall be substituted, namely: —

"(f) Potency. — The potency shall be determined by the microbiological method for the estimation of vitamin B12 activity as specified in the edition of the Indian Pharmacopoeia for the time being and shall be not less than that stated on the label".

(iii) In Part XII, in clause (E): —

(a) in the headline the word 'Extract' shall be omitted;

(b) in item '2' relating to Liver Concentrate:—

i) in the third paragraph, the following sentence shall be omitted, whereas: —

"It may contain 0.1 percent of benzoic acid or a suitable concentration of other harmless preservative";

ii) in the fourth paragraph, at the end the following sentence shall be inserted, namely: —

"It may contain 0.1 percent of benzoic acid or a suitable concentration of other harmless preservatives".

(c) in the item 5 relating to Proteolysed Liver: —

i) in the third paragraph for the figure and letters "2 mcg" the following figure and letters shall be substituted;

"4 mcg."

ii) in the fourth paragraph, for the word 'formal' the word "formol" shall be substituted;

iii) at the end the following paragraphs shall be inserted, namely:

*"Manner of Labelling Preparation of Liver for oral use"*. Subject to the other provisions of these rules and this Schedule a preparation of Liver for oral use for which standards have been laid down in this Part of Schedule shall bear on the label the name of the preparation as prescribed.

In case the preparation of Liver for oral use is presented as a paste, the word 'paste' shall be added after the name prescribed and the solid content, weight/weight, shall also be stated on the label.

In case any patent or proprietary preparation contains one or more of the preparations of Liver for oral use prescribed above, the formula of such a patent or proprietary preparation shall show the name or names, as the case may be, of the preparation or preparations prescribed in this Part and the quantity which shall be expresed on dry bais when the paste is used".

(38) in Schedule K;

i) against item 13 in column I, under the heading "Class of Drugs", for sub-items (a) to (e) beginning with "(a) Castor Oil" and ending with "(e) Quinine tablets" the following items shall be substituted, namely: —

"1) Aspirin tablets.
2) A. P. C. tablets and powders.
3) Analgesic Balms.
4) Antacid preparations.
5) Gripe Water for use of infants.
6) Inhalers, containing drugs for treatment of cold and nasal congestion.
7) Syrups, lozenges, pills and tablets for cough.
8) Liniments for external use.
9) Skin ointments and ointments for burns.
10) Absorbent cotton wool, bandages, absorbent gauze and adhesive plaster.
11) Castor oil, liquid Paraffin and Epsom Salt.
12) Eucalyptus oil.
13) Tincture Iodine, Tincture Benzoin Co. and Mercurochrome solution in containers not exceeding 100 ml.
14) Tablets of Quinine Sulphate I. P.
15) Tablets of Iodochlorohydroxy Quinoline — 250 mg".

ii) after item 18 and the entries relating thereto the following item and entries shall be added, namely: —

| Class of Drugs | Extent and conditions of exemption |
|---|---|
| 19. Hair Fixers, namely mucilagenous preparations containing gums, used by men for fixing beard. | The provisions of Chapter IV of the Act and the rules thereunder". |

39. in Schedule M under the para '(2) Requirements of Plant and equipment';

(i) in sub-paras (A), (B), (C), (D), for figures and words '300 square feet' the figures and words '30 square metres' shall be substituted;

(ii) in sub-para (E), for the figures and words '200 square feet' the figures and words '20 square metres' shall be substituted;

(iii) in sub-paras (F) for figures and words '300 square feet' the figures and words '30 square metres' shall be substituted;

(iv) in sub-para (G) for the figures and words '250 square feet' the figures and words '25 square metres' shall be substituted;

(v) in sub-paras (H) and (I) for the figures and words '200 square feet' the figures and words '20 square metres' shall be substituted.

(vi) in sub-para (O) for figures and words '300 square feet' the figures and words '30 square metres' shall be substituted;

(vii) in sub-para (K) for the figures and words '600 square feet' the figures and words '60 square metres' shall be substituted.

40. for Schedule 'N', the following Schedule shall be substituted: —

SCHEDULE 'N'

(See rule 64(1))

**List of minimum equipment for the efficient running of a Pharmacy: —**

I. Entrance — The front of a pharmacy shall bear an inscription "Pharmacy".

II. Premises — The premises of pharmacy shall be separated from rooms for private use. The premises shall be wellbuilt, dry, well-lit and ventilated and, of sufficient dimensions to allow the goods in stock, especially medicaments and poisons to be kept in a clearly visible and appropriate manner. The area of the Section to be used as dispensing department shall be not less than 6 sq. metres for one pharmacist working therein with additional 2 sq. metres for each additional pharmacist. The hight of the premises shall be at least 2.5 metres.

The floor of the Pharmacy shall be smooth and washable. The walls shall be plastered or tiled or oil painted so as to maintain smooth, durable and washable surface devoid of holes, cracks and crevices.

A Pharmacy shall be provided with ample supply of good quality water.

The dispensing department shall be separated by a barrier to prevent the admission of the public.

III. Furniture and apparatus — The furniture and apparatus of a Pharmacy shall be adapted to the uses for which they are intended and correspond to the size and requirements of the establishment.

Drugs, chemicals, and medicaments shall be kept in a room appropriate to their properties and in such special containers as will prevent any deterioration of the contents or of the contents of containers kept near them. Drawers, glasses and other containers used for keeping medicaments shall be of suitable size and capable of being closed tightly to prevent the entry of dust.

Every container shall bear a label of appropriate size, easily readable, with names of medicaments as given in the Pharmacopoeias.

A Pharmacy shall be provided with a dispensing bench, the top of which shall be covered with washable and impervious material like stainless steel, laminated or plastic, etc.

A Pharmacy shall be provided with a cupboard with lock and key for the storage of poisons and shall be clearly marked with the word 'POISON' in red letters on a white background.

Containers of all concentrated solutions shall bear special label or marked with the words 'To be diluted'.

A Pharmacy shall be provided with the following minimum apparatus and books necessary for making of official preparations and prescriptions: —

**Apparatus: —**

Balance, dispensing, sensitivity 30 mg.
Balance, counter, capacity 3 Kgm. sensitivity 1 gm.
Beakers, lipped, assorted seizes.
Bottles, prescription, ungraduated assorted sizes.
Corks assorted sizes and tapers.
Cork, extracter.
Evaporating dishes; porcelain.
Filter paper.
Funnels, glass.
Litmus paper, blue and red.
Measure glasses cylindrical 10 ml., 25 ml. 100 ml., and 500 ml.
Mortars and pestles, glass.
Mortars and pestles, wedgwood.
Ointment pots with bakelite or suitable caps.
Ointment slab, porcelain.
Pipettes, graduated, 2 ml. 5 ml. and 10 ml.
Ring, stand (retort) iron, complete with rings.
Rubber stamps and pad.
Scissors.
Spatulas, rubber or vulcanite.
Spatulas, stainless steel.
Spirit lamp.
Glass stirring rods.
Thermometer, O° to 200°C
Tripod stand.
Watch glasses.
Water bath.
Water distillation still in case Eye drops and Eye lotions are prepared.
Weights, Metric, 1 mg. to 100 gm.
Wire Gauze.
* Pill finisher, boxwood.
* Pill Machine.
* Pill Boxes.
* Suppository mould.

**Books:**

The Indian Pharmacopoeia (Current Edition)
National Formulary of India (Current Edition)
The Drugs and Cosmetics Act, 1940.
The Drugs and Cosmetics Rules, 1945.
The Pharmacy Act, 1948.
The Dangerous Drugs Act, 1930.

IV. General Provisions — A pharmacy shall be conducted under the continuous personal supervision of a Registered Pharmacist whose name shall be displayed conspicuously in the premises.

The Pharmacist shall always put on clean white overalls.

The premises and fittings of the Pharmacy shall be properly kept and everything shall be in good order and clean.

All records and registers shall be maintained in accordance with the laws in force.

Any container taken from the poison cupboard shall be replaced therein immediately after use and the cupboard locked. The keys of the poison cupboard shall be kept in the personal custody of the responsible person.

Medicaments when supplied shall have labels conforming to the provisions of laws in force.

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Note. — The above requirements are subject to modifications at the discretion of the licensing authority, if he is of opinion that having regard to the nature of drugs dispensed, compounded or prepared by the licensee, it is necessary to relax the above requirements or to impose additional requirements in the circumstances of a particular case. The decision of the licensing authority in that regard shall be final.

* These items are to be provided only by those who intend to dispense pills or suppositories as the case may be.

Sd/-

RAMESH BAHADUR

Under Secretary to the Government of India

THE SCHEDULE

**Particulars of the drafts published for amending further the Drugs and Cosmetics Rules, 1945**

| Sr. No. | Short title of the rules | No. of the Drug and Cosmetics Rules, 1945 proposed to be amended | Notification No. and date | Part No., date and page of the Gazette of India in which notification has been published | Date on which the Gazette copies were made available to the public | The last date fixed for receipt of objections and suggestions from persons likely to be affected by the proposed amendment |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 1. | The Drugs and Cosmetics (Amendment) Rules, 1970. | Rule 2 — Clause (ee) | 1-57/68-D dated 19-1-1970. | Part II — Section 3 (ii) S.O. 345 dated 31-1-70 Page 610-611. | 2-2-1970 | 15th April, 1970. |
| 2. | — do — | New Rule 3-A | 1-23/70-D dated 30-3-1970. | Part II — Section 3 (ii) S.O. 1336 dated 11-4-70 Page 1849. | 13-4-1970 | 20th June, 1970. |
| 3. | — do — | New Rule 32-A | 1-127/69-D dated 18-4-1970. | Part II — Section 3(ii) S. O. 1555 dated 2-5-70 Page 2088. | 4-5-1970 | 16th July, 1970. |
| 4. | — do — | Rule 45. | 1-127/69-D dated 18-4-1970. | — do — | — do — | — do — |
| 5. | The Drugs and Cosmetics (Amendment) Rules, 1969. | Rule 49 — Proviso to this Rule. | 1-100/68-D dated 26-5-1969. | Part II — Section 3(ii) S.O. 2181 dated 7-6-69 Pages 2273-2274. | 9-6-1969 | 31st August, 1969. |
| 6. | — do — | Rule 50. | 1-53/68-D dated 10-4-1969. | Part II — Section 3(ii) S.O. 1458 dated 19-4-69 Page 1368. | 24-4-1969 | 25th June, 1969 |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| 7. | The Drugs and Cosmetics (Amendment) Rules, 1969. | Rule 50(3) Proviso to the sub-rule 3. | 1-46/68-D dated 3-6-1969. | Part II — Section 3(ii) S. O. 2257 dated 14-6-69 Page 2408. | 16-6-1969 | 31st August, 1969. |
| 8. | — do — | Rule 63 — Proviso to the Rule. | — do — | — do — | — do — | — do — |
| 9. | — do — | Rule 65 — Sub-rule (3). | 1-4/68-D dated 13-3-1969. | Part II — Section 3(ii) S.O. 1113 dated 22-3-69 Pages 1098-1099. | 24-3-1969 | 30th May, 1969. |
| 10. | — do — | Rule 65 — New Sub-rule (11-A) | 1-20/67-D dated 3-12-1969. | Part II — Section 3(ii) S.O. 4962 dated 20-12-69 Page 5375. | 22-12-1969 | 20th February, 1970. |
| 11. | The Drugs and Cosmetics (Amendment) Rules, 1968. | Rule 65 — Sub-rule (12) | 1-23/68-D dated 29-11-1968. | Part II — Section 3(ii) S. O. 4414 dated 14-12-68 Page 5619. | 16-12-1968 | 15th March, 1969. |
| 12. | The Drugs and Cosmetics (Amendment) Rules, 1969. | New Rule 65-A. | 1-15/68-D dated 21-5-1969. | Part II — Section 3(ii) S.O. 2110 dated 31-5-69 Page 2239. | 2-6-1969 | 31st August, 1969. |
| 13. | The Drugs and Cosmetics (Amendment) Rules, 1968. | Rule 66 — Proviso to sub-rule (1) | 1-6/67-D dated 1-6-1968. | Part II — Section 3(ii) S. O. 2094 dated 15-6-68 Page 2960. | 17-6-1968 | 1st September, 1968. |
| 14. | The Drugs and Cosmetics (Amendment) Rules, 1969. | Rule 67-A Proviso to sub-rule (2) | 1-46/68-D dated 3-6-1969. | Part II — Section 3(ii) S.O. 2257 dated 14-6-69 Page 2408. | 16-6-1969 | 31st August, 1969. |
| 15. | — do — | Rule 67-E Proviso to the Rule. | — do — | — do — | — do — | — do — |
| 16. | — do — | New Rule 67-H Existing Rule 67-H to be renumbered as 67 | 1-15/68-D dated 21-5-1969. | Part II — Section 3(ii) S.O. 2110 dated 31-5-69 Page 2238. | 2-6-1969 | — do — |
| 17. | The Drugs and Cosmetics (Amendment) Rules, 1968. | Rule 67-H Proviso to sub-rule (1) | 1-6/67-D dated 1-6-1968. | Part II — Section 3(ii) S.O. 2094 dated 15-6-68 Page 2960. | 17-6-1968 | 1st September, 1968. |
| 18. | The Drugs and Cosmetics (Amendment) Rules, 1969. | Rule 69 — Sub-rule (2) | 1-12/67-D dated 12-3-1969. | Part II — Section 3(ii) S.O. 1112 dated 22-3-69 Pages 1097-1098. | 24-3-1969 | 30th May, 1969. |
| 19. | — do — | Rule 69-A Sub-rule (3) | 1-46/68-D dated 3-6-1969. | Part II — Section 3(ii) S.O. 2257 dated 14-6-69 Page 2408. | 16-6-1969 | 31st August, 1969. |
| 20. | — do — | Rule 69-A Proviso to sub-rule (1) | — do — | — do — | — do — | — do — |
| 21. | The Drugs and Cosmetics (Amendment) Rules, 1970. | Rule 71-A-Clause (2) | 1-127/69-D dated 18-4-1970. | Part II — Section 3 (ii) S.O. 1555 dated 2-5-70 Page 2088. | 4-5-1970 | 16th July, 1970. |
| 22. | The Drugs and Cosmetics (Amendment) Rules, 1969. | Rule 72 — Proviso to this Rule. | 1-46/68-D dated 3-6-1969. | Part II — Section 3 (ii) S.O. 2257 dated 14-6-69 Page 2408. | 16-6-1969 | 31st August, 1969. |
| 23. | — do — | Rule 73 AA Proviso to the Rule. | — do — | Part II — Section 3 (ii) S.O. 2257 dated 14-6-69 Page 2409. | — do — | — do — |
| 24. | — do — | Rule 75 Proviso to the Rule. | — do — | — do — | — do — | — do — |
| 25. | — do — | Rule 75-A Proviso to sub-rule (1) | — do — | — do — | — do — | — do — |
| 26. | — do — | Rule 77 — Proviso to the Rule. | 1-46/68-D dated 3-6-1969. | — do — | — do — | — do — |
| 27. | — do — | Rule 83-AA Proviso to the Rule. | — do — | — do — | — do — | — do — |
| 28. | The Drugs and Cosmetics (Amendment) Rules, 1968. | New Rule 84-A | 1-15/63-D dated 25-10-1968. | Part II — Section 3 (ii) S.O. 3867 dated 2-11-68 Pages 4894-4895. | 4-11-1968 | 31st January, 1969. |
| 29. | The Drugs and Cosmetics (Amendment) Rules, 1969. | New Rule 84-AA | 1-15/68-D dated 21-5-1969. | Part II — Section 3 (ii) S.O. 2110 dated 31-5-69 Pages 2239-2240. | 2-6-1969 | 31st August, 1969. |
| 30. | — do — | Rule 85-B Sub-rule (3). | 1-46/68-D dated 3-6-1969. | Part II — Section 3 (ii) S.O. 2257 dated 14-6-69 Page 2409. | 16-6-1969 | — do — |

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| 31. | The Drugs and Cosmetics (Amendment) Rules, 1969. | Rule 85-F Proviso to the Rule. | 1-46/68-D dated 3-6-1969. | Part II — Section 3 (ii) S.O. 2257 dated 14-6-69 Page 2409 | 16-6-1969 | 31st August, 1969. |
| 32. | — do — | New Rule 85-I the existing Rule 85-I to be renumbered as Rule 85-J. | 1-15/68-D dated 21-5-1969. | Part II — Section 3 (ii) S.O. 2110 dated 31-5-69 Page 2240. | 2-5-1969 | — do — |
| 33. | The Drugs and Cosmetics (Amendment) Rules, 1968. | Rule 96 — New Sub-rule (1-A) | 1-6/65-D dated 19-2-1968. | Part II — Section 3 (ii) S. O. 772 dated 2-3-68 Pages 1231-1232. | 4-3-1968 | 10th May, 1968. |
| 34. | The Drugs and Cosmetics (Amendment) Rules, 1970. | Rule 106-A Explanation to clause (ii) of Sub-rule (B). | 1-127/69-D dated 18-4-1970. | Part II — Section 3(ii) S.O. 1555 dated 2-5-70 Page 2089. | 4-5-1970 | 16th July, 1970. |
| 35. | The Drugs and Cosmetics (Amendment) Rules, 1969. | Rule 138-sub-rule (2) and Proviso to sub-rule (2). | 1-46/68-D dated 3-6-1969. | Part II — Section 3 (ii) S.O. 2257 dated 14-6-69 Pages 2409-2410. | 16-6-1969 | 31st August, 1969. |
| 36. | — do — | Rule 140 Proviso to the Rule. | — do — | Part II — Section 3 (ii) S.O. 2257 dated 14-6-69 Pages -2410. | — do — | — do — |
| 37. | — do — | New Rule 142-A. | 1-15/68-D dated 21-5-1969. | Part II — Section 3 (ii) S.O. 2110 dated 31-5-69 Page 2240. | 2-6-1969 | — do — |
| 38. | — do — | New Rule 145-A. | 1-44/68-D dated 23-4-69. | Part II — Section 3 (ii) S.O. 1761 dated 10-5-69 Page 1662. | 12-5-1969 | 25th June, 1969. |
| 39. | — do — | New Rule 145-B. | | — do — | — do — | — do — |
| 40. | — do — | Schedule-A Forms 16 & 17. | — do — | Part II — Section 3 (ii) S.O. 1761 dated 10-5-69 Pages 1662-1663. | — do — | — do — |
| 41. | The Drugs and Cosmetics (Amendment) Rules, 1970. | Schedule-A Form 21. | 1-9/70-D dated 17-4-1970. | Part II — Section 3 (ii) S.O. 1554 dated 2-5-70 Page 2088. | 4-5-1970 | 15th July, 1970. |
| 42. | The Drugs and Cosmetics (Amendment) Rules, 1968. | Schedule-F Part I Section (B). | 1-3/68-D dated 30-12-1968. | Part II — Section 3 (ii) S.O. 127 dated 11-1-69 Pages 181-187. | 13-1-1969 | 15th March, 1969. |
| 43. | The Drugs and Cosmetics (Amendment) Rules, 1969. | Schedule-F Part IX. | 1-10/69-D dated 26-5-1969 | Part II — Section 3 (ii) S. O. 2180 dated 7-6-69 Pages 2272-2273. | 9-6-1969 | 31st August, 1969. |
| 44. | — do — | Schedule-F Part XII. | — do — | — do — | — do — | — do — |
| 45. | The Drugs and Cosmetics (Amendment) Rules, 1970. | Schedule-K. | 1-127/69-D dated 18-4-1970. | Part II — Section 3 (ii) S.O. 1555 dated 2-5-70 Page 2089. | 4-5-1970 | 16th July, 1970. |
| 46. | — do — | Schedule-K New entry 19. | — do — | — do — | — do — | — do — |
| 47. | The Drugs and Cosmetics (Amendment) Rules, 1969. | Schedule-M. | 1-2/68-D Dated 11-6-1969. | Part II — Section 3 (ii) S.O. 2360 dated 21-6-69 Page 2478. | 23-6-1969 | 15th September, 1969. |
| 48. | — do — | Schedule-N. | 1-17/68-D dated 16-6-1969. | Part II — Section 3 (ii) S. O. 2481 dated 28-6-69 Pages 2612-2614. | 30-6-1969 | 10th September, |

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